Laboratory Bulletin

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Utah Department of Health

Division of Epidemiology and Laboratory Services
Bureau of Laboratory Improvement
Web page: http://health.utah.gov/els/labimp **November 2003**

Introducing

Nancy Bishop	Technical Services
Donald Cogswell	Chemistry
Stephanie McGee	Bacteriology
Michael Mortensen	Chemistry
Paul Ellingson	Lab Improvement

NOTEWORTHY

☛ **GLUCOLA OUT, JELLYBEANS IN?:** Daniel M. Baer, MD stated in the October 2003 Medical Laboratory Observer (MLO) there are two studies reporting substituting jellybeans for the 50 gram glucose load in glucose tolerance testing. Dr. Baer reports Lamar's study using 28 jellybeans was effective. Lamar used a specific jellybean brand composed of sugar, corn syrup, modified cornstarch and dextrose.

Dr. Baer cautions the candy may not work as well as the liquid at the higher test load used for non-gestational diabetes testing or at a time interval greater than one hour. He also states the diabetes incidence was so low in the study population that it might not be an accurate study design. The advantage is jellybeans are better tolerated by the patient than the glucose liquid.

☛ **BLOOD STORAGE EMERGENCIES:**

What is your plan to maintain an adequate blood supply should your power go out? What if the power is out for several days like the East Coast blackout in August?

Even if you have a generator that will maintain your blood bank refrigerator, can you survive without additional donor draws or contract blood delivery? Your emergency planning should have viable blood storage options for at least three days. You should also plan actions to take if no more blood can be collected or delivered.

☛ **HIPAA FOR – NOT AGAINST THE PATIENT:** In August the Health Insurance Portability and Accountability Act (HIPAA) regulation was modified to allow information disclosure for patient care, billing and standard health care operations. A lab can give patient reports over the phone or fax to health care providers as long as the lab has a way to ensure such information goes to the appropriate individual.

Contents

When the patient signs the standard release form to allow information necessary for appropriate care, the lab can give test results to the patient's clinicians, lab QA staff, case management staff, and regulatory inspectors without obtaining additional, specific permission. The lab should notify the patient their policies are available upon request. It is not necessary to give every patient a copy (few people will want to read them).

The lab must have the original patient signed release forms available. The lab must have a policy to ensure patients with special needs (hearing impairment, poor reading skills, visual impairment, comprehension problems) can understand the written forms and policies. HIPAA should never compromise patient care.

☛ **MAMMASTATIN TEST:** Biomedical Diagnostics developed an immunoblot assay for a semiquantitative determination of mammastatin protein in serum. ARUP Laboratories, in Salt Lake City, has worldwide market and service rights for the assay. Mammastatin, a growth-inhibitor, may indicate breast cancer risk. Early studies relate low values to a 1-in-3 to 1-in-6 cancer risk. A high level result could reassure patients their cancer risk is low at the present time. The Food and Drug Administration (FDA) classified the test "research use only". Biomedical Diagnostics is completing an application for FDA pre-market approval.

☛ **U.S. POSTAL REGULATIONS REVISED:** June 12, 2003 the Postal Service revised their regulations for transporting hazardous materials to more closely reflect the International Air Transport Association (IATA) standards. Changes include:

- biohazard symbol use clarified
- four risk groups compatible with World Health Organization (WHO) criteria
- packaging defined by risk group class

You may read the entire regulation at http://www.gpoaccess.gov/fr/retrieve.html Select the 2003 Federal Register Vol. 68 option. Near the bottom of the page, enter page #33858 in the space provided and click submit. You will be on the federal register page that lists Postal Service 39 CFR Part 111 where the revised regulation begins. You will need Acrobat Reader to view the document.

☛ **UTAH COMMUNICABLE DISEASE RULE R386-702:** Three infectious diseases have been added to the "reportable" category. SARS, small pox and monkey pox are now reportable in Utah. The rule clarified immediate reporting to occur within 24 hours and non-immediate reporting to occur within three days. For information call Epidemiology at 801-538-6191.

☛ **ISI CALIBRATION FOR POINT-OF-CARE COAGULATION TESTING DEVICES**: Dr. Leon Poller in Manchester, England, published his research in the American Journal of Clinical Pathology (2002;117:892-899). He and his colleagues studied two different whole blood coagulation testing systems to determine if they could reduce the number of patient samples necessary to calibrate a new reagent lot. While calibration precision and International Normalized Ratio (INR) deviation were not greatly affected by reducing the number of patients tested, International Sensitivity Index (ISI) calibration was less precise compared with conventional manual testing. The authors recommend the World Health Organization (WHO) standard of testing 60 warfarin stabilized patients and 20 healthy subjects for prothrombin time sensitivity index calibration continue.

☛ **INTERFERENCE WITH WHOLE BLOOD GLUCOSE MONITORS:** The following is from an FDA Consumer Drug Information Sheet (posted 2/14/2003).

"If your glucose monitor or test strips use a glucose dehydrogenase pyrroloquinolinequinone (GDH PQQ) method, using EXTRANEAL may cause a falsely high glucose reading. A false high blood glucose reading could cause you to give more insulin than you need. Getting more insulin than you need can lower your blood sugar unnecessarily and can cause a serious reaction

including loss of consciousness. You or your health care provider should contact the manufacturer(s) of the monitor and test strips you use to make sure that Extraneal, icodextrin or maltose will not interfere with the test results."

Extraneal is a new peritoneal dialysis solution. The active ingredient is icodextrin which interacts with some whole blood glucose test methods.

The entire sheet is on the FDA website at: www.fda.gov/cder/consumerinfo/druginfo/Extraneal.htm.

☛ **WNV – LULL BEFORE THE STORM:** West Nile Virus (WNV) came to Utah this year. The first human case occurred in a Uintah County resident in September. Next year clinicians may see significantly more human cases. In the endemic parts of the country, clinicians are noting patients with very mild cases of disease that do not progress to the central nervous system. These milder cases are called 'West Nile Fever' or 'West Nile Flu'.

During the first year the virus entered the United States, everyone infected could develop an antibody titer that was diagnostic for disease. Now that the virus has been in the country several seasons, a positive titer may not represent current disease. Clinicians will need to look for a rise in titer to be certain the patient did not acquire a "mild" infection last season. Laboratories should require acute and convalescent phase sera for testing. The patient's current symptoms may not be due to WNV disease even if they have a titer to the virus.

Influenza season may overlap West Nile season. Clinical symptoms can be similar. While influenza is more important to epidemiology in terms of morbidity and mortality, West Nile gets better press. Telling the various viral diseases apart may not mean much difference to patient care, but in controlling disease spread it is vital.

For the latest information on WNV in Utah check www.health.utah.gov/wnv.

☛ **HEINZ BODY QC:** Robert Novak, MD, from the Children's Hospital in Akron, Ohio, responded to a question in CAP Today on what a lab can use for Heinz body quality control. Dr. Novak stated a lab may obtain a blood sample (with appropriate permission) from a person with Hb Zurich or one with a spleenectomy. Alternatively, the lab can use anticoagulated blood that is stored at room temperature long enough to produce Heinz bodies. Older blood at room temperature induces Heinz body formation.

Dr. Novak recommends each lab determine or validate its reference range as different staining methods can induce Heinz body formation. Test the age range of your patient population for the "normal" range. Make certain blood used for the range is the same "age" as patient testing will be.

Dr. Novak concludes "Fortunately, individuals with true Heinz body anemias often demonstrate multiple Heinz bodies in more than 50 percent of cells, levels that far exceed those seen in healthy people."

FROM THE PATIENT'S CHART

"Patient's medical history has been remarkably insignificant with only a 40 pound weight gain in the past three days."

☆ Feature ☆

ROOT CAUSE ANALYSIS

Did you ever investigate a quality control or proficiency test failure, find the cause, fix it, and have another failure soon after the first? For example, you decide testing personnel did not mix the new hematology control vial thoroughly before opening it. You have a meeting and train

personnel on proper mixing technique for a new quality control vial. You observe the mixing process for the next few days. The end of the week the controls fail again. Why? The real cause of the quality control failure was not identified and corrected. You can continue with trial and error attempts to fix the problem (recalibrate is a common 'fix'), or you can apply the standard principle called "root cause analysis".

The March/April 2003 issue of COLA's *Insights* has an excellent article, "Expect the Unexpected: Incident Management Readiness". In the article laboratories are cautioned against investigating errors to find out whom to blame and how to correct the person's behavior. Most errors are caused by a faulty process – not a person. Even when a person makes an error, there is a cause for the error that is seldom willful. You cannot solve any problem until you find the real cause. How many times have the Utah CLIA surveyors heard "we fired that person and hired a new manager" as a plan of correction to deficient practices? How many times has that solution worked in 15 years? Once.

COLA's article states: "A simple 'root cause analysis' is performed by repeatedly asking 'why.' Continuing to ask 'why' at least five times will dig progressively deeper to reach the root cause of the situation. Root cause is also referred to as true cause.

A 'root cause analysis' is the investigation into the causal factors that lead to the outcome of an event. Causal factors include equipment problems, control problems, or human errors.

Often a root cause analysis simply identifies these causal factors and makes recommendations to correct them. This may prevent the same event from recurring, but if the 'root' cause is not addressed, the event is likely to repeat in the future. Root causes are the weaknesses in the system that allows the causal factors to occur. Systems are the processes an organization has in place to ensure patient safety and to encourage personnel to take appropriate actions and discourage them from taking inappropriate actions.
The focus should be on the systems and processes, not individual performance. Examples include written procedures and instructions, maintenance and calibration, and standards and policies.

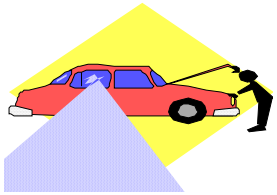
The 'root cause analysis' includes mapping out the events and circumstances surrounding the event. Although not required as part of an Incident Management Plan, flowcharting of the incident might provide a useful visual representation of the occurrence. All causal factors, barriers, and system issues are identified with an indication of how each impacted the incident.

Once all the facts of a case are known and the root cause is identified, a corrective action plan is developed and implemented. The final step is to follow-up within a determined amount of time to ensure that the corrective action plan is effective. The analysis must be thorough and credible."

Author: Catherine Johnson, MT(ASCP)
Educational Services Division Manager

How many times have the Utah CLIA surveyors seen this approach work? Always.

For a copy of the entire article call COLA at 1-800-981-9883.



CLIA BITS:

ADDITIONAL WAIVED TESTS:

° Instant Technologies Istrep Strep A

° Pan Probe Biotech Earlydetect Menopause Test

° Beckman Coulter ICON SC Strep A

° Binax NOW RSV Test

° Integrated Biotechnology Quick Lab RSV Test

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FEDERAL SANCTIONS FOR 2002

The list of clinical laboratories sanctioned by CMS during 2002 was published in the Federal Register recently. Utah had three facilities that made the list. Each facility had a specialty or subspecialty removed from their certificate for repeated proficiency test failures and/or quality failures discovered during inspection. For a complete listing check the CLIA website at www.cms.gov/CLIA.

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FINAL CLIA REGULATIONS

Here are some additional requirements and clarifications from the April, 2003, final regulation. Access the complete regulation from the link at our website (top of page 1 of this bulletin).

(CRIL 95-47) "For all of the microbiology subspecialties, the total process of isolation and identification of microorganisms is considered a complete test system that is categorized as high complexity. In bacteriology, mycology, and mycobacteriology; specimen processing, primary inoculation of culture media, and staining are only portions of testing and are not categorized separately for complexity."

Rotate quality control testing among all testing personnel and all shifts. The requirement is for two levels of control to be run each calendar day – not a period of 24 hours. For example, you do a blood type and crossmatch on November 10 at 1 p.m. (the only one that day). You have an emergency type and hold at 6 a.m. on November 11. It has not been 24 hours (1 day) since you did controls, so you don't need to do them again unless you get another test request after 1 p.m. – right? Wrong, once each calendar day.

During the FY 04 and FY 05 inspection cycles, only deficiencies affecting patient outcome or potential outcome will be cited. No deficiencies will be written for deleted regulations. Until the federal computer system is updated, a regulation cite crosswalk is available from the state agencies.

Cytology:

Liquid-based Pap smears count as one slide, not half a slide as they did previously. Liquid-based non-gynecologic preparations still count as one-half slide for workload limit calculations.

Gynecologic/histologic correlation is only required for HSIL, adenocarcinoma or other malignant neoplasms - not all malignant and premalignant lesions as formerly required.

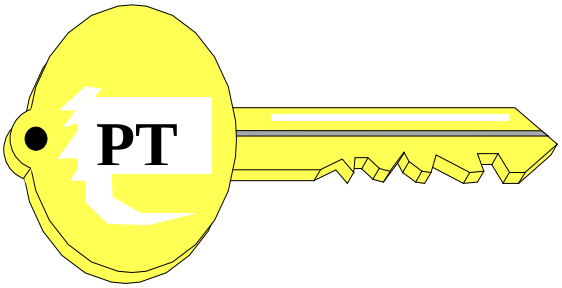
The pathology lab needs to determine annually the number of abnormal Pap smears that have histology correlation. The old rule required a correlation with the number of histopathology slides that correlated with their corresponding pap smears. The new regulation should make the statistical correlation easier for the pathology lab.

The final regulation states that labs using automated or semi-automated screening devices must follow the CLIA quality control requirements as well as the manufacturer's.

The instructions for setting a cytotech's workload limit are more explicit.

Equals

"1000 cubic centimeters of wet socks = 1 literhosen"



API announced new surveys for 2004: CSF & Body Fluid Analysis, Fetal Fibronectin, Sysmex X Series, Quantitative D-Dimer, i-Stat ACT, Hemochron Jr. ACT, Mycology, Legionella Antigen Detection, High Sensitivity CRP, Quantitative CRP, and Direct Antiglobulin Testing. For information call 1-800-333-0958.

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CAP added 30 new surveys to their 2004 menu – including Anti-HIV-1 Survey that is compatible with the MedMira Reveal and OraQuick Rapid HIV-1 Antibody test kits. This survey includes an option to report HIV-1 Western Blot test results. For information call 1-800-323-4040 option 1.

Safety Tips

POST PHLEBOTOMY PATIENT SAFETY

Dennis Ernst, MT(ASCP), responded to a question in the October issue of MLO regarding the safety of having a person bend their arm to stop the bleeding after phlebotomy. Mr. Ernst is the Director of the Center for Phlebotomy Education Inc. in Ramsey, IN. He quotes the National Committee for Clinical Laboratory Standards (NCCLS) guidelines that instruct the phlebotomist to place a gauze pad over the site and apply continuing mild pressure. He further states that most text books warn against asking the patient to bend the arm or apply pressure themselves to the puncture site. Mr. Ernst reminds phlebotomists the responsibility for applying pressure and preventing bleeding complications or bruising is theirs.

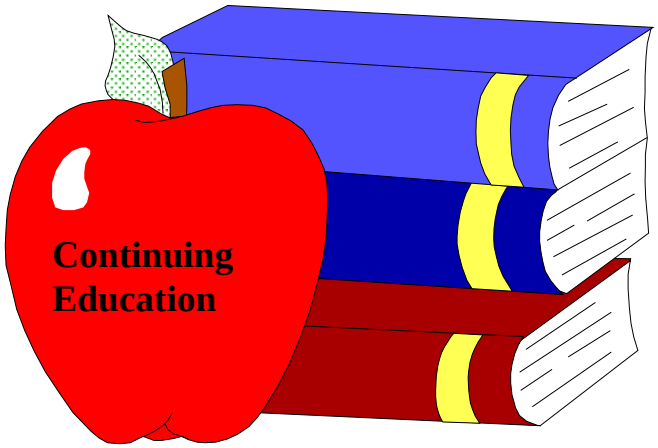
* *

Terry Jo Gile, MT(ASCP), MA Ed, wrote an article for the August edition of MLO entitled “Are you wearing the right lab coat?” She refers to OSHA’s compliance document CPL 2-2.69. The regulation is specific on what is necessary to comply with the American Society for Testing and Materials for personal protective lab coats. Three measurements of a coat’s ability to protect the worker include spray rating, air porosity and the Suter hydrostatic resistance to fluid pressure. Traditional cotton lab coats do not protect you from infectious fluid penetration.

Ms. Gile concludes the ideal spray rating for lab coat fabrics to make them fluid resistant is 90. The air porosity should be 10 or higher. The Suter hydrostatic resistance should be 340 or more. Check with your manufacturer or supplier for the ratings on any fluid resistant coat. Does your lab coat meet these requirements after 100 washings? If not, you are not protected from infectious spills, splashes or squirts.

There are companies making fluid resistant, cool and comfortable lab coats. Check around.

“Do not do what you would undo if caught.” Author Unknown



1. NCCLS – NEW DOCUMENTS

EP6-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach

EP21-A Estimation of Total Analytical Error for Clinical Laboratory Methods
ISO 15189 Medical laboratories – Particular requirements for quality and competence

M24-A Susceptibility Testing of Mycobacteria, Nocardiae and Other Aerobic Actinomycetes

M42-R Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals

MM5-A Nucleic Acid Amplification Assays for Molecular Hematopathology

2. UTAH LENDING LIBRARY ADDITIONS

Video: "Packaging & Shipping of Infectious Materials", Satellite program by the Alabama Department of Health and the NLTN, 2.5 hours, 0.2 CEU's available from CDC.

3. SOFTWARE RECALL BY FDA

FDA posted a Class I recall notice for Misys Healthcare Systems laboratory information system software used to manage patient specimens in the laboratory for patient diagnosis and treatment. Versions 5.2, 5.23 and 5.3 demonstrated a defect that could result in quality assurance information being excluded from the patient report. Using the defective software system could allow potentially life-threatening results to be released directly to patients without quality assessment validation.

Read the entire recall notice at:

www.fda.gov/medwatch/SAFETY/2003/safety03.htm#misys.

1999 British GCSE exam results from 16 year olds:

Q: Name a major disease associated with cigarettes

A: Premature death